

Attorney Docket No.: KBI-0004
Inventors: Ranganathan et al.
Serial No.: 09/855,346
Filing Date: May 15, 2001
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This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

Claims 1 - 3 (canceled).

Claim 4 (re-presented - formerly dependent claim 1): ~~The pharmaceutical composition of claim 1 further comprising A pharmaceutical composition to alleviate the symptoms of uremia comprising a composition of a probiotic, a prebiotic, a sorbent for inorganic phosphate, and an adsorbent for specific uremic solutes other than urea and an ammoniaphilic urea degrading microorganism with high alkaline pH stability and high urease activity, said composition being microencapsulated or enteric coated with a material designed to deliver the probiotic, the prebiotic, and ammoniaphilic urea degrading microorganism to their site of action in relatively native form without binding of digestive materials to the composition prior to reaching the target region, wherein said prebiotic ensures the viability of the probiotic, and wherein said microencapsulated or enteric coating prevents the release of the ammoniaphilic urea degrading microorganism into the patient.~~

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Claim 5 (original): The pharmaceutical composition of claim 4 wherein the inorganic phosphate adsorbent is selected from aluminum hydroxide gel, calcium hydroxide gel and magnesium hydroxide gel and the specific uremic solute adsorbent is activated charcoal.

Claims 6-9 (canceled).

Claim 10 (previously amended): A pharmaceutical composition to alleviate the symptoms of uremia comprising a composition of a probiotic, a prebiotic, an ammoniaphilic urea degrading microorganism with high alkaline pH stability and high urease activity, a water absorbent, a sorbent for inorganic phosphate and an adsorbent for specific uremic solutes other than urea, said composition being microencapsulated or enteric coated with a material designed to deliver the probiotic, the prebiotic, and ammoniaphilic urea degrading microorganism to their site of action in relatively native form without binding of digestive materials to the composition prior to reaching the target region, and wherein said microencapsulated or enteric coating prevents the infection of a patient from the ammoniaphilic urea degrading microorganism.

Claims 11-16 (previously canceled).

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Listing of Claims:

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2 | Claim 1 (currently amended): A pharmaceutical composition to
alleviate the symptoms of uremia comprising a composition of a
probiotic, a prebiotic, and an ammoniaphilic urea degrading
microorganism with high alkaline pH stability and high urease
activity, said composition being microencapsulated or enteric
coated with a material designed to deliver the probiotic, ~~a~~ the
prebiotic, and ammoniaphilic urea degrading microorganism to their
site of action in relatively native form without binding of ~~various~~
digestive materials to the ~~sorbents~~ composition prior to reaching
the target region, wherein said prebiotic ensures the viability of
the probiotic, and ~~prevent infection of a patient from wherein said~~
microencapsulated or enteric coating prevents the release of the
ammoniaphilic urea degrading microorganism into the patient.

Claim 2 (original): The pharmaceutical composition of claim 1
further comprising a water absorbent.

Claim 3 (original): The pharmaceutical composition of claim 2
where the water absorbent is selected from locust bean gum,
psyllium fiber, guar gum and zeolite.

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Claims 4 (original): The pharmaceutical composition further comprising a sorbent for inorganic phosphate and an adsorbent for specific uremic solutes other than urea.

Claim 5 (original): The pharmaceutical composition of claim 4 wherein the inorganic phosphate adsorbent is selected from aluminum hydroxide gel, calcium hydroxide gel and magnesium hydroxide gel and the specific uremic solute adsorbent is activated charcoal.

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Claims 6 (original): The pharmaceutical composition of claim 1 where the probiotic is selected from a *Bifidium* or *Lactobacillus* species.

Claims 7 (original): The pharmaceutical composition of claim 1 wherein the prebiotic is selected from fructan oligosaccharide and araban oligosaccharide.

Claim 8 (original): The pharmaceutical composition of claim 1 wherein the ammoniaphilic bacteria is selected from *Bacillus pasteurii*, *Sporosarcina ureae*, *Bacillus* species and *Lactobacillus* species KB-I.

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Claim 9 (original): The pharmaceutical composition of claim 1 wherein the probiotic and the ammoniaphilic urea degrading microorganism with high alkaline pH stability and high urease activity comprise the same species of bacteria.

β_1 Claim 10 (currently amended): A pharmaceutical composition to alleviate the symptoms of uremia comprising a composition of a probiotic, a prebiotic, an ammoniaphilic urea degrading microorganism with high alkaline pH stability and high urease activity, a water absorbent, a sorbent for inorganic phosphate and an adsorbent for specific uremic solutes other than urea, said composition being microencapsulated or enteric coated with a material designed to deliver the probiotic, ~~a~~ the prebiotic, and ammoniaphilic urea degrading microorganism to their site of action in relatively native form without binding of ~~various~~ digestive materials to the ~~sorbents~~ composition prior to reaching the target region, and ~~prevent~~ wherein said microencapsulated or enteric coating prevents the infection of a patient from the ammoniaphilic urea degrading microorganism.

Claims 11-16 (canceled)
